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E-Cigarettes: Are They Safe?

What is an e-cigarette?

Electronic cigarettes, e-cigarettes or vaporized cigarettes are all different names to describe a battery-operated device that provides inhaled doses of nicotine or a non-nicotine vaporized solution.

E-cigarettes, designed to mimic cigarettes, have been on the market since the early 2000's and were first imported from China. There are several designs, but they all take some form of an elongated cigarette. As with a typical cigarette, smoke bellows from the tip of the device. In fact, because it is often difficult to discern if the smoker is smoking a regular cigarette or an using an electronic cigarette, some jurisdictions in the United States have proposed banning e-cigarette sales simply from the standpoint that it is increasingly difficult for jurisdictions to enforce existing smoking regulations with the introduction of these devices to the marketplace, since it is not always clear whether someone is smoking a cigarette, in violation of clean indoor air laws, or not.

The answer to the question, "What is an e-cigarette?", however, is more complex than the description above suggests. Some have claimed that they are a substitute for a cigarette and should therefore be considered a tobacco product. Others claim that they are a smoking cessation device, and that the nicotine makes them akin to nicotine

gum or other products used to help smokers quit smoking. As long as the question of "What is an e-cigarette?" remains only partially answered, a consensus will not develop on how to best regulate these products.

Regulation of E-cigarettes

E-cigarettes have increased in popularity since first made available domestically. Due to concerns raised by the public's escalating use of e-cigarettes and uncertainty of the safety of their chemical content, the FDA banned all imports of e-cigarettes into the United States in 2008. This ban was made under its authority to regulate "drugs" or "drug delivery devices".

Consequently, in 2009 one of the banned e-cigarette manufacturers sued the federal government because they did not believe the FDA had the authority to regulate e-cigarettes as "drugs" or "drug delivery devices" under the Federal Food Drug and Cosmetic Act. Therefore, the manufacturer claimed the FDA could not prevent e-cigarette shipments from entering the country. The manufacturer asked the courts for an injunction to prohibit the FDA from continuing its ban on e-cigarette import shipments.

In January 2010, the U.S. District Court of Appeals for the District of Columbia agreed with the e-cigarette manufacturer and held that the FDA may not regulate e-cigarettes as a drug or drug

The FDA is concerned about the safety of these products and how they are marketed to the public. More research must be done to determine whether e-cigarettes can be proven safe to the user and effective as a smoking cessation tool.

delivery device. Instead, because the nicotine contained in the e-cigarette cartridges is derived from tobacco, the court held that the FDA may regulate them as a tobacco product under the Family Smoking Prevention and Tobacco Control Act (TCA).

The FDA appealed the lower court's ruling to the federal Court of Appeals and last month, a three-judge panel of the federal Court of Appeals issued its opinion agreeing with the lower court decision. It held that marketed its product as a tobacco cessation aid (such as nicotine gum or patches),

Some health and medical professionals associations, including the AMA, ACS, AHA, ALA and the Campaign for Tobacco Free Kids advocate for a strong regulatory role by the FDA. Others, including the American Academy of Pediatrics, call for a complete ban on e-cigarettes.

the FDA did not have authority to regulate e-cigarettes as a drug or drug delivery device.

The FDA wished to have e-cigarettes included under the Federal Food Drug and Cosmetic Act's authority (i.e., as a drug or drug delivery device) because that Act's standards are more stringent and require the clinical testing of products. The court's decision limits the FDA's ability to test e-cigarettes for safety and prohibits it from banning e-cigarettes entirely. However, the TCA expressly allows state and local governments to regulate the sale or use of tobacco products, which would include e-cigarettes. Currently, there are no prohibitions against e-cigarettes in Illinois. The FDA has filed an *en banc* petition, asking the entire D.C. Court of Appeals to hold a new hearing and review the decision of the three-judge panel. If

the decision is upheld by the *en banc* panel, then the FDA may choose to appeal the ruling to the U.S. Supreme Court.

Current Regulatory Status

The FDA still may have the authority to regulate e-cigarettes that are expressly marketed as a smoking cessation aid under its power to regulate drugs or drug delivery devices. If so, the FDA could conduct safety tests on these e-cigarettes, ban e-cigarettes that it finds unsafe, or require a doctor's prescription to obtain e-cigarettes marketed as a smoking cessation aid.

Based upon the Appeals Court's ruling, the FDA could issue regulations of e-cigarettes as a tobacco product under the TCA. However, this law prohibits the FDA from completely banning the sale of tobacco products or requiring a doctor's prescription to purchase tobacco products, but it could potentially ban the marketing and sale to certain groups, such as minors.

Are E-Cigarettes Safe?

At this point, the safety of e-cigarettes is essentially unknown because their testing has been very limited due to the preceding court actions. Additionally, there is no clear consensus among tobacco prevention advocates as to what e-cigarettes are, e.g., are they an effective harm reduction tool? Is their use the first step in nicotine addiction? Some advocates see e-cigarettes as a potentially effective harm reduction tool to assist current smokers wishing to quit smoking and believe that the nicotine contained in them is no more potent than that found in nicotine replacement aids,

while others believe their sale should be banned because there are too many unknowns and there is the distinct possibility that e-cigarettes could lead to cigarette addiction.

What can be said with some degree of certainty is that:

- There is no scientific evidence that e-cigarettes are safer for consumers than regular tobacco products.
- There is no scientific evidence that e-cigarettes can help smokers quit, which is often how they are marketed, if not directly by the manufacturers than by distributors at the point of sale.

There currently are not any federal and only limited local and state legal age restrictions for e-cigarette sales. With limited regulation on e-cigarettes, parents and guardians are particularly concerned about youth purchasing these products, especially as some brands are being enhanced with flavors such as bubble gum and other fruit flavors. As with other tobacco flavored products, flavoring is often added to better entice youth to experiment with e-cigarettes.

Until the pending legal proceedings reach a firm conclusion and additional laboratory testing is conducted by the FDA, the efficacy and safety of e-cigarettes continues to be open to debate and the public is left to make its own judgments as to their overall safety.